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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,077	10/19/2000	Ilya Ravkin	VAI 301B	7890

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EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/694,077	Applicant(s) RAVKIN ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 22 July 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 34-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 34-47 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 19 October 2000 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on July 22, 2005.

Status of the Claims

2. Claims 34-47 are pending.

3. Please note: Applicant's elected species (Subgroup 1: carrier = particle comprising the following four properties: fused fiber of various colors, glass, polygonal viewing surface, transparent region; Subgroup 2: analyte = oligonucleotide attached covalently; Subgroup 3 = CCD camera) was found in the art. See MPEP § 803.02 (emphasis added):

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species***. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

4. Therefore, claims 34-47 are examined on the merits in this action.

Response to Restriction and/or Election of Species

5. Applicant's election of species is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

6. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Priority/Specification

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e) as follows:

A. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application <u>by application number</u> (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a nonprovisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Here, the application number for 60/241,714 has not been included.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 34, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over and Lam et al. (Lam, K. S.; Salmon, S. E.; Hersh, E. M.; Hruby, V. J.; Kazmierski, W. M.; Knapp, R. J. "A new type of synthetic peptide library for identifying ligand-binding activity" Nature **1991**, 354, 82-84) and Egner et al. (Egner, B. J.; Rana, S.; Smith, H.; Bouloc, N.; Freg, J. G.; Brocklesby, W. S.; Bradley, M. "Tagging in combinatorial chemistry: the use of coloured and fluorescent beads" Chem. Commun., **1997**, 735-736).

For ***claims 34***, Lam et al. (see entire document) teach a method for identifying ligand-binding activity using a synthetic 'one-bead, one-peptide' approach (e.g., see

abstract), which reads on the claimed invention. For example, Lam et al. disclose providing a first class of particles in a first reaction vessel and a second class of particles in a second reaction vessel wherein a first type of analyte is attached to said first class of particles and a second type of analyte is attached to said second class of particles (e.g., see page 82, column 1, last paragraph, "The first cycle consisted of distributing a pool of resin beads into separate reaction vessels each with a single amino acid [i.e., different class of analyte]"; see also figure 1, wherein the first class = A, second class = G, etc. and each class is in its own reaction vessel; see also page 82, column 2, paragraph 3 describing formation of pentapeptide library with ~2,476,099 members). Lam et al. also disclose forming a mixture of particles from the first and second vessels, the mixture having substantially equal numbers of particles for each vessel (e.g., see figure 1, "randomization" step; see also page 82, column 1, last paragraph, "Our method involves creating a large peptide library ... representing the universe of possible random peptides in roughly equimolar proportion"). Lam et al. further disclose dispersing a portion of the mixture to an examination site on a surface, the particles of the first and second classes being distrubted to random positions across the examination site (e.g., see figure 2; see also page 82, column 2, paragraph 1). Lam et al. further disclose reacting the portion of the mixture with a test substance such as a labeled antibody against β-endorphin or streptavidin (e.g., see Tables 1 and 2; see also figure 2). Lam et al. also disclose acquiring at least one image of particles at the examination site on the surface (e.g., see figure 2 showing low- and high-power photomicrographs).

For ***claim 39***, Lam et al. disclose covalent attachment of pentapeptide sequences (e.g., see figure 1; see also abstract).

For ***claim 40***, Lam et al. disclose a reaction step that occurs before the dispensing step (e.g., see Lam et al., page 82, column 2, paragraph 1, "Acceptor molecules were ... added in soluble form to the peptide-bead library [i.e., before analysis]"). Also note that optimization of process steps, especially with respect to ordering, is within the routine skill of the art. *In re Burhans*, 154 F.2d 690, 69 USPQ330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results).

The prior art teachings of Lam et al. differ from the claimed invention as follows:

For ***claims 34***, Lam et al. are deficient in that they do not specifically teach the use of a first and second optically detectable code to interpret the result of such a binding experiment. Lam et al. only teach the use instead labels such as alkaline phosphatase coupled with various sequencing techniques to identify petapeptides that interact with the ligands. Lam et al. also fail

However, Egner et al. teach the following limitations that are deficient in Lam et al.:

For ***claims 34***, Egner et al. (see entire document) teach the use of a first and second class of detectable codes to aid in the identification of a library of peptides bound to beads (e.g., see figures 1 and 4; see also Footnotes disclosing that various dyes can be used to label each "class" of library member, for example, pyrene butanoic acid = Val, methyl red = Ala, etc.).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make to use the coloured and fluorescently labeled beads as disclosed by Egner et al. to make the peptide library as disclosed by Lam et al. for the purposes of facile high throughput screening because Egner et al. explicitly states that their labeled beads were created for this purpose and uses the Lam et al. reference as an example of a preferred embodiment (e.g., see Egner et al., page 736, paragraph bridging columns 1-2, "The <u>use of coloured and fluorescent beads</u> has the potential, we believe, to simplify the identification of library members for <u>single bead screening application</u>"; see also page 735, column 1, paragraph 3, wherein the Lam et al. article is explicitly cited in footnote number 2). Furthermore, one of ordinary skill in the art would have been motivated to use the coloured and labeled beads as taught by Egner et al. because according to Egner et al. it is a "simple" technique that is "non-destructive" and "very sensitive, with detection levels easily down to femtomoles of material/bead" (e.g., see Egner, et al., page 736, column 1, last paragraph). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Egner et al. actually use the method of Lam et al. to synthesize their library (e.g., see Egner et al, page 735, column 1, paragraph 3 wherein the Lam et al. reference is cited for the library preparation in footnote 2).

10. Claims 34-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al. (Lam, K. S.; Salmon, S. E.; Hersh, E. M.; Hruby, V. J.; Kazmierski, W. M.; Knapp, R. J. "A new type of synthetic peptide library for identifying ligand-binding activity" Nature **1991**, 354, 82-

84) and Egner et al. (Egner, B. J.; Rana, S.; Smith, H.; Bouloc, N.; Freg, J. G.; Brocklesby, W. S.; Bradley, M. "Tagging in combinatorial chemistry: the use of coloured and fluorescent beads" Chem. Commun., **1997**, 735-736) and Lee (U.S. Patent No. 4,053,433) (Date of Patent is **1977**) and Blawas et al (Blawas, A.S.; Reicher, W. M. "Protein Patterning" Biomaterials **1998** *19*, 595-609) and Noonan et al (U.S. Patent No. 6,129,896) (Filing Date is **December 17, 1998**) and Walt (U.S. Patent No. 6,210,910) (Filed **March 2, 1998**).

For ***claims 34 and 41***, Lam et al. (see entire document) teach a method for identifying ligand-binding activity using a synthetic 'one-bead, one-peptide' approach (e.g., see abstract), which reads on the claimed invention. For example, Lam et al. disclose providing a first class of particles in a first reaction vessel and a second class of particles in a second reaction vessel wherein a first type of analyte is attached to said first class of particles and a second type of analyte is attached to said second class of particles (e.g., see page 82, column 1, last paragraph, "The first cycle consisted of distributing a pool of resin beads into <u>separate reaction vessels</u> each with a single amino acid [i.e., different class of analyte]"; see also figure 1, wherein the first class = A, second class = G, etc. and each class is in its own reaction vessel; see also page 82, column 2, paragraph 3 describing formation of pentapeptide library with ~2,476,099 members). Lam et al. also disclose forming a mixture of particles from the first and second vessels, the mixture having substantially equal numbers of particles for each vessel (e.g., see figure 1, "randomization" step; see also page 82, column 1, last paragraph, "Our method involves creating a large peptide library ... representing the universe of possible random peptides in <u>roughly equimolar proportion</u>"). Lam et al. further disclose dispersing a portion of the

mixture to an examination site on a surface, the particles of the first and second classes being distrubted to random positions across the examination site (e.g., see figure 2; see also page 82, column 2, paragraph 1). Lam et al. further disclose reacting the portion of the mixture with a test substance such as a labeled antibody against β-endorphin or streptavidin (e.g., see Tables 1 and 2; see also figure 2). Lam et al. also disclose acquiring at least one image of particles at the examination site on the surface (e.g., see figure 2 showing low- and high-power photomicrographs).

For ***claims 39 and 46***, Lam et al. disclose covalent attachment of pentapeptide sequences (e.g., see figure 1; see also abstract).

For ***claims 40 and 47***, Lam et al. disclose a reaction step that occurs before the dispensing step (e.g., see Lam et al., page 82, column 2, paragraph 1, "Acceptor molecules were … added in soluble form to the peptide-bead library [i.e., before analysis]"). Also note that optimization of process steps, especially with respect to ordering, is within the routine skill of the art. *In re Burhans*, 154 F.2d 690, 69 USPQ330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results).

<u>The combined references of Lam et al. and Egner et al. differ from the claimed invention as follows</u>:

For ***claims 35 and 42***, the combined references of Lam et al. and Egner et al. fail to teach at least one flat viewing surface and a shape that self-orients the viewing surface to face a viewing direction substantially perpendicular to the surface. Lam et al. only teach the use of round beads.

For ***claims 36 and 43***, the combined references of Lam et al. and Egner et al. fail to teach each particle has at least one transparent portion.

For ***claims 37 and 44***, the combined references of Lam et al. and Egner et al. fail to teach carriers as a combination of fused fibers of various colors, the colors and relative positions of the fibers indicating the code.

For ***claim 38 and 45***, the combined references of Lam et al. and Egner et al. fail to teach the attachment of biological cells to the particles for cell identification. The combined references of Lam et al. and Egner et al. only teach the use of peptides.

For ***claim 41***, the combined references of Lam et al. and Egner et al. fail to teach the additional steps of acquiring a set of images of particles at the examination site, each image corresponding to a different spectral band an operating via the use of a computer program to identify particles of the same class by using the images to develop a mask for the particles of the same class, and detecting one or more reporting modalities within the mask. The combined references of Lam et al. and Egner et al. only disclose imagining different spectral bands and the use of filter masks (e.g., see figures 1 and 2), but the references is silent as to whether a "computer" program takes advantage of these measurements for identification.

<u>However, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach the following limitations that are deficient in Lam et al. and Egner et al.</u>:

For ***claims 35 and 42***, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach that the microcarriers can have generally a flat shape with two

substantially parallel planar sides (e.g., see Lee, figures 2-5 disclosing examples of a planar "top" and a planar "bottom" side that are substantially parallel and flat).

For ***claims 36 and 43***, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach a transparent portion (e.g., see Lee, column 3, lines 60-62, "A list of suitable colors may include: Clear").

For ***claims 37 and 44***, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach fused colored fibers wherein said fibers represent the code (e.g., see Lee, figures 2-5, see also column abstract, see also column 2, Summary of Invention, wherein the code is detectable on either planar side; see also column 4, lines 49-52, "A preferred type of color-coded microparticle ... consists of microscopic pieces of colored plastic films fused together to form a rectangular 'microsandwich'"; see also column 4, lines 46-48; see also, column 2, line 46 disclosing 233,846,052 uniquely coded batches of microcarriers; see also see figure 5 disclosing fused fibers).

For ***claims 38 and 45***, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach the attachment of biological cells to the particles for cell identification. For example, Noonan et al and Blawas et al teach the use of fused glass and/or plastic fibers can be cut into chips and used as biosensors to attach biological cells (e.g., see Noonan et al, column 2, lines 23-26; see also column 2, last three paragraphs, "Method 100 begins by synthesizing functional moieties onto a plurality of fibers ... For example, functional moieties may include DNA oligonucleotides for DNA testing biosensor devices. Alternative, the functional moieties may include proteins, peptide, Antibodies"; see also Blawas et al, pages 605-606, section 4.3, wherein Blawas et al

disclose that bound <u>proteins and/or antibodies can be used to control the areas of cell adhesion</u> and/or growth to a substrate surface i.e., the cells bind to the proteins that are attached to the fused glass and/or plastic chips).

For ***claim 41***, the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. teach the use of a computerized sensor array for randomly detecting a mixed population of sells wherein each individual cell in the are is positioned in an optically addressable microwell (e.g., see Walt et al., abstract; see also column 5, lines 57 through column 6, line 20; see also column 7, lines 24-40; see also figures 1 and 3; see also column 12, lines 59-65). Each cell population is individually encoded with a single fluorophores or chromophore or ratios of such dyes like the as was disclosed by Egner et al. (e.g., see Walt et al., column 7, lines 24-40; column 15, lines 15 through column 20, lines 31; column 19, line 66 though column 20, line 11) and the identity and location of each cell type is determined by the characteristic optical response signature of the fluorophores or chromophore dye or ratios of such dyes (e.g., see Walt et al., column 15, lines 25-42; column 16, lines 18-26; column 20, lines 12-31). The type of cell includes adipocyte fat cells, neurons, and fibroblasts. The apparatus for the optical detection of the cells includes instruments such as epifluorescence microscope and CCD camera and the data is processed by a computer using an image processing software (e.g., see Walt et al., column 26, lines 28-55).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use taggants as taught by the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. in place of the colored beads as taught by the

combined references of Lam et al. and Egner et al. because the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. expressly states that these taggants are useful for labeling chemicals (e.g., see Lee, abstract), which would encompass the peptide "chemicals" disclosed by the combined references of Lam et al. and Egner et al. Furthermore, one of ordinary skill in the art would have been motivated to use the taggants disclosed by the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. because the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. demonstrates that an enormous number of codes can be generated, which is exactly what is required for labeling combinatorial libraries (e.g., see Lee, column 2, lines 22-23, see also lines 28-45, "The improvement ... comprises providing microparticles ... [that] are encoded according to, a particular orderly sequence of visually color distinguishable dyed and/or pigmented layers ... For example, using a library of 12 colors in an eight-membered sequence, wherein no color is used adjacent to itself, the number of codes would be determined as follows ... this system includes 233,846,052 possible codes"). Finally, a person of skill in the art would reasonably have been expected to be successful because the combined references of Lee, Blawas et al., Noonan et al., and Walt et al. discloses the use of a microscope to analyze the particles, which would encompass the microscopic techniques disclosed by the combined references of Egner et al. and Lam et al. (e.g., see Lee, column 1, line 32; see also Summary of the Invention).

In addition, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make colored coded microparticle tags (i.e., microcarriers) as taught by Lee, Lam et al. and Egner et al. for the purpose of tagging

cells as taught by the combined references of Noonan et al., Blawas et al. and Walt et al. and thus attaching said cells to said tags because Noonan et al., Blawas et al. and Walt et al. explicitly teach that fused glass fiber chips like the ones disclosed by Lee are a preferred embodiment because they are cheap to make (i.e., see Noonan et al., abstract, column 2, Summary of the Invention) and that these biosensors could detect that attachment of biological cells (e.g., see Blawas et al., page 605-606, section 4.3; see also Background of the invention, see also Table 1). A person of skill in the art would have been motivated to use the color coded fused glass and/or plastic disclosed by Lee as biosensors for detecting cells as disclosed by the combined teachings of Noonan et al. and Blawas et al. because Noonan et al., explicitly states that the use of bundled fibers (like the ones disclosed by Lee) are a "preferred embodiment" (e.g., see column 2, paragraph 2, "the bonded fiber; see also column 2, last two paragraphs, see also column 1, paragraph 2). Furthermore, Blawas et al. discloses that immobilized biomolecules can be beneficially used to monitor cell adhesion and/or growth (e.g., see entire document, especially, section 4.3 and figure 5). Furthermore, Walt et al. disclose that their sensor offers, "distinct advantages to high throughput screening of combinatorial libraries where hundreds of thousands of candidate compounds must be evaluated" (e.g., see Walt et al., Summary of Invention) and is particularly useful for screening cells using single or mixed dyes One of ordinary skill in the art would have reasonably expected to be successful because all three references disclose that fused glass and/or plastic can be used (e.g., see Blawas et al., Table I, Substrate column; see also Noonan et al., column 3, line 1; see also Lee, column 4, line 51). Furthermore, a person of skill in the art would have

reasonably expected to be successful using the sensor as disclosed by Walt et al. because Walt et al. teach that both single fluorophoric or chromophoric dye can be used for encoding the cells or, in an alternative embodiment, two or more encoding materials or dyes may be used to encode cell populations and the optical response intensity ratios for the dyes, produced by exposure to excitation light energy, are employed to encode and identify members of the cell population with the array, which would encompass the methods of Egner et al.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
November 11, 2005